REMARKS

I. Status of Claims

Prior to the present amendment, Claims 25-33 are pending in the application, among which claim 32 is withdrawn from consideration and the remaining claims are examined and rejected in the present Office Action.

By this amendment, Claim 25 is amended, Claims 29 and 30 are cancelled, and Claims 34-38 are added.

After entry of this amendment, claims 25-28, 31-38 are pending in the application.

II. Amendment of Claims

Claim 25 has been amended whereby the following changes have been made:

(1) The phrases "for stabilizing the composition" and "an auxiliary agent which is different that water" are deleted. These phrases were added to claim 25 in a previous amendment.

(2) The Markush-type language "selected from gabapentin or pregabalin" is changed to read "selected from the group consisting of gabapentin and pregabalin," in accordance with the Examiner's suggestion.

(3) A limitation "wherein the pharmaceutical composition is a liquid" is added. Support for the recitation of "liquid" can be found in the original specification and claims, for example page 13, lines 9-13, 24-26, the paragraph spanning page 39 and 40, Examples 1-3, and original claims 5 and 6.

(4) A limitation "wherein as compared with a second composition that contains the same components as the pharmaceutical composition except for the absence of the α amino acid, after the pharmaceutical composition and the second composition each have been stored in a sealed container at 45 °C for 2 weeks the amount of lactam that is formed in the pharmaceutical composition relative to the initial amount of the 4-amino-3-substituted-butanoic acid derivative in the pharmaceutical composition is less than the amount of lactam that is formed in the second composition relative to the initial amount of the 4-amino-3-substituted-butanoic acid derivative in the second composition" is added. Support for this amendment can be found in the specification as filed, for example, page 6, lines 2-12, and Examples 1-3.

Claim 29, which depended from Claim 25 and recited a "liquid" composition, is deleted as its subject matter is incorporated into Claim 25 as amended.

Claim 30, which depended from Claim 25 and recited a "solid" composition, is deleted and its subject mater is incorporated into new Claim 34.

New Claims 34-38 correspond to existing Claims 25-28 and 31, respectively, with the exception that these new claims refer to a "solid" pharmaceutical composition instead of a "liquid" one and that claim 34 recites a storage temperature of "60 °C" instead of "45 °C" recited in claim 25. Support for the recitation of the storage temperature of "60 °C" can be found in Examples 4-7 in the application as filed.

No new matter has been added by this amendment. By the action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

III. Claim Objections

Claim 25 is objected to because of the alleged improper Markush-type language "selected from gabapentin or pregabalin." The language at issue has been amended to read "selected from the group consisting of gabapentin and pregabalin," exactly as the Examiner suggested. Accordingly, the objection is overcome.

IV. New Matter

The amendment filed on May 27, 2005, is objected to allegedly because it introduces new matter by the addition of the phrase "auxiliary agent which is different than water" in Claim 25. The phrase at issue has been deleted from Claim 25 by this amendment, as required by the Examiner. Accordingly, the rejection is overcome.

V. Claim Rejection under 35 U.S.C. § 112

Claims 25-31 are rejected under 35 U.S.C. § 112, first paragraph, allegedly for failure to comply with the written description requirement. Specifically, the Examiner alleged that the limitation "auxiliary agent which is different than water," which was added to independent Claim

25 by the previous amendment, fails to find support in the original specification. Applicant believes that there is adequate support in the original specification for the limitation at issue. Nonetheless, to expedite the allowance of the application, Applicant has amended Claim 25 to delete the language at issue. As a result, the rejection to Claim 25, as well as Claims 26-31, which are dependent from claim 25, is overcome. New claims 34-38 do not recite the language at issue; therefore, the rejection to Claims 25-31 here does not apply to the new claims.

VI. Claim Rejection under 35 U.S.C. § 102

Claims 25-27, 29, and 31 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Woodruff (US 5,084,479).

Applicant respectfully submits that Woodruff does not anticipate Claims 25-27 and 29, as amended, because it does not disclose all limitations of these claims. (MPEP §2130) For example, Claim 25 as amended recites a limitation regarding the relative amount of lactam formed in the composition after storage. Woodruff does not disclose this limitation. Woodruff discloses a preparation of a solution for use in laboratory experimental studies. There is an absolute lack of disclosure about the lactam amount in the solution. Claims 26, 27, 29, and 31 depend directly or indirectly from claim 25 and, thus, include all limitations of claim 25. As Woodruff does not anticipate claim 25, it does not anticipate 26, 27, 29, or 31 either.

New Claims 34-38 also include the limitation referred to above. For the same reasons detailed above for Claims 25-27, 29, and 31, Woodruff does not anticipate these claims either. Moreover, Claims 34-38 include another limitation that "the pharmaceutical composition is a solid." Because Woodruff discloses only a solution, as the Examiner acknowledged, not a solid, it can not anticipate the claimed pharmaceutical composition that is solid.

V. Claims Rejection under 35 U.S.C. §103

Claims 25-31 and 33 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Robson et al. (US 4,126,684) in view of Costa et al. (US 5,248,678). The Examiner states that "Robson discloses a composition comprising baclofen, alpha amino acid such as glycine, auxiliary agent (i.e., manitol, lactose, etc...) and aqueous gelatin solution. See Example 2." The Examiner further states, "Costa is being supplied as the reference to demonstrate the art recognized functional equivalent of gabapentin and baclofen as GABA

agonists." The Examiner concludes, "It would have been obvious to make the gabapentin and glycine combination since the examiner takes Official Notice of the equivalence of gabapentin and baclofen as GABA agonists." The Office action in the third paragraph on page 6 made a reference to "Seiler." Applicant believes that this is a typographical error and that the Office Action intended to refer to "Robson et al. (US 4,126,684)" instead, since the Office Action clearly states at the bottom paragraph of page 5 that "Claims 25-31 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Robson et al. (US 4126684) in view of Costa et al. (US 5248678)", without providing a citation for "Seiler." Accordingly, in this response Applicant regards the reference to "Seiler" as a reference to Robson et al. (US 4,126,684). Applicant respectfully submits that a *prima facie* case of obviousness has not been established in the present application.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP §2143) Applicant respectfully submits that none of the three basic criteria has been met.

Specifically, Applicant believes that the references fail to teach or suggest all claim limitations. For example, claim 25 as amended and new claim 34 include a limitation that the relative amount of lactam in the claimed composition is less as compared to a composition without the α amino acid after storage of the compositions under specified conditions. The references, individually or in combination, do not teach or suggest this limitation. There is simply no teaching in Robson et al. or Costa et al. at all that the relative amount of lactam in the composition containing baclofen and glycine would be lower as compared with a composition without glycine after storage of the compositions under certain conditions, not even mentioning of lactam or the amount of lactam in the composition, or stability of the composition.

Further, Applicant believes that there is no suggestion or motivation, nor a reasonable expectation of success, to modify Robson et al. or to combine the teachings of Robson et al. and

Costa et al. Robson et al. relates to a composition that includes an addicting agent and baclofen. The intended purpose of combining baclofen with addicting agents in the composition is to prevent future addiction or to ameliorate the withdrawal symptoms in the addicted. (See Robson, et al., column 1, lines 29-34. emphasis added.). There is no teaching in Robson et al. that this intended purpose would also be served by a composition that contains gabapentin in the place of baclofen. More over, according to Robson et al., the basis for including baclofen in the composition is the surprising finding that "4-amino-3-p-halophenylbutyric acids and derivatives, especially baclofen . . . actually depress the symptoms of withdrawal of addicting agents and reduces the craving for the addicting agents. . . ". (See Robson et al., column 1, lines 21-33). There is no teaching in Robson et al. that gabapentin also has the above property or utility of baclofen. To the contrary, Robson et al. teach that gabapentin is not expected to have the same property as Robson et al. disclose that the above property of baclofen was "surprisingly" found. (See Robson et al., column 1, lines 21-33). Therefore, Robson et al. in fact teach away from substituting baclofen with gabapentin. In view of the reasons detailed above, a person skilled in the art would not have been motivated, nor have a reasonable expectation of success, to substitute baclofen with gabapentin to arrive at the claimed invention.

The secondary reference Costa et al., according to the Examiner, is being supplied as the reference to demonstrate the art recognized "functional equivalent of gabapentin and baclofen as GABA agonist." However, the cited references disclose no connection between the properties or utility of baclofen that are disclosed in Robson et al. and GABA agonist activity of baclofen on the other hand. In the absence of such connection, a person skilled in the art would not be motivated, nor have a reasonable expectation of success, to substitute baclofen in the composition disclosed in Robson et al with gabapentin to arrive at the claimed invention, despite the alleged functional equivalency of gabapentin and baclofen as GABA agonist.

Moreover, as indicated above, Claim 25 as amended and new Claim 34 recite a limitation that the relative amount of lactam in the claimed composition is lower as compared to a composition without the α amino acid after storage of the compositions under specified conditions. Further as explained above, there is simply no teaching in Robson et al. or Costa et al. that the relative amount of lactam in the composition containing glycine and baclofen or any other GABA analogs would be lower as compared with a composition without glycine after

storage of the compositions, not even mentioning of the relative amount of lactam in the composition or stability of the composition containing baclofen. Therefore, the cited references provide no motivation, nor reasonable expectation of success, to modify the composition disclosed in Robson et al. in view of Costa et al. to arrive at the claimed composition.

VI. Double Patenting

Claims 25-31 and 33 are rejected under the judicially created doctrine of double patenting over claims 28-39 of co-pending US Application No. 09/674,819. Applicant respectfully submits that this rejection is improper because US Application No. 09/674,819 has not yet issued as patent and no actual double patenting rejection may be properly made over claims of a co-pending application. (MPEP 804)

VII. Concluding Remarks

In view of the amendments and the foregoing remarks, Applicant respectfully requests reconsideration of the matter and the withdrawal of all the rejections and objections. Applicant believes that the application is now in order for allowance and, accordingly, respectfully requests timely issuance of a Notice of Allowance.

Respectfully submitted,

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